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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,666	01/29/2004	Cheryl A. Conover	07039-221003	5410

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FISH & RICHARDSON P.C.
3300 DAIN RAUSCHER PLAZA
60 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,666	CONOVER ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1-29-04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 13 recite "an article for manufacturing" is confusing because it is unclear as to whether this limitation is a kit or an apparatus.

4. Claim 13, recite that the anti-PAPP-A antibody "can be" used for measuring PAPP-A level in a sample renders the claim as being conditional and therefore indefinite because it is unclear if this antibody is actually performing this function.

5. Claim 15, recite polypeptides selected from the group consisting of "high sensitivity C-reactive protein" is vague because it is unclear whether "high sensitivity" is part of the group that wherein the polypeptides are selected from. Please clarify.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Meisser et al (Biology of Reproduction, (1985) Vol. 33, No. 5, pp. 1073-1077).

Claims 15-16 are drawn to an article of manufacture for diagnosing an inflammatory condition in a non-pregnant patient, comprising reagents for; measuring levels of a plurality of polypeptides in a biological sample from said patient, wherein said plurality of polypeptides comprises PAPP-A and one or more of the polypeptides selected form the group consisting of high sensitivity C-reactive protein, creatine kinase MD, troponin I, troponin T, creatine kinase, creatinine, fibrinogen, interleukin-1 and interleukin-6, wherein the biological sample is could be whole blood, plasma or serum.

Meisser et al teaches reagents for measuring levels of a plurality of polypeptides in a biological sample by disclosing that PAPP-A polypeptides concentrations are higher in plasma compared to serum obtained from the same patient, together with the fact that PAPP-A binds heparin prompted a study of PAPP-A and a clotting system. It was determined that pure PAPP-A inhibits thrombin-induced coagulation of citrated plasma. Meisser realized the effect of PAPP-A was similar to that of heparin and used that property to develop a bioassay and thrombin-induced polymerization of purified fibrinogen was measured in a spectrophotometer. Thrombin activity was plotted against the concentration of PAPP-A to give a linear relationship (see abstract).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 13-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Overgaard et al (WO 00/54806) in view of Zuk et al (USP#4,444,879).

The claims are drawn to an article of manufacture for diagnosing an inflammatory condition in a non-pregnant patient, comprising anti-PAPP-A antibody and packaging material, wherein PAPP-A is used for measuring PAPP-A levels in a biological sample and packaging material comprises a label or package insert indicating that the anti-PAPP-A antibody can be used for diagnosing inflammatory conditions.

Overgaard et al teaches that the identification of PAPP-A provides methods for screening of altered proliferation states in non-pregnant patients, including growth-promoting states (page 1, lines 13-20) that indicate inflammatory conditions such as restenosis and atherosclerosis (page 1, lines 26-30). In one embodiment, an anti-PAPP-A monoclonal antibody in the form of a pharmaceutical solution was administered

to a patient that included excipients for controlling the release of a compound in vivo (page 16, lines 1-10). Detectable labels for PAPP-A activity can be radioactive isotopes such as 125 I or 32 P (page 12, lines 6-34). The biological sample used from the patient is blood (page 39, claim 9).

The reference of Overgaard et al does not teach a packaging material including a label or package insert etc.

However, Zuk et al teach that it is a matter of convenience to include reagents of an immunoassay in a kit where the reagents are in predetermined ratios so as to substantially optimize the sensitivity of the assay in the range of interest (column 22, lines 63-66).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the reference of Overgaard et al that teaches methods and reagents for measuring levels of PAPP-A proteins, and format the reagents into a kit because Zuk et al teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. One would be motivated because kits are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Although the reference does not specifically disclose that a kit would have instructions, which teach how to use said kit, it would have been prima facie obvious to include instructions which describe how to perform the assay.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Bayes-Genis et al (Pregnancy-Associated Plasma Protein A as a marker of Acute Coronary Syndromes, New England Journal of Medicine, Volume 345:1022-1029, No. 14, pages 1-14), teaches that PAPP-A plasma proteins which are found in both men and women, might be a marker that could identify patients with unstable atherosclerotic plaques.

B. Meisser et al (In vitro effects of pregnancy-associated plasma protein-A: artifacts due to heparin, Biology of Reproduction (1988), Vol. 39(2), pages 373-378), teaches PAPP-A has been known to inhibit elastase activity and thrombin-induced coagulation of fibrinogen.

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah A. Davis
Remsen Bldg.
Room 3D58
September 24, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600